WYETH-AYERST RESEARCH

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Division of American Home Products Corporation

U.S. REGULATORY AFFAIRS

May 24, 1999

Dockets Management Branch, HFA-305
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99D-0484

Dear Sir or Madam,

Wyeth-Ayerst Laboratories, a Division of American Home Products Corporation, respectfully submits comments to Docket No. 99D-0484 regarding the draft guidance for industry entitled "Accelerated Approval Products- Submission of Promotional Materials."

Wyeth-Ayerst Laboratories is a major research-oriented pharmaceutical company with leading products in the areas of women's health care, cardiovascular disease therapies, central nervous system drugs, anti-inflammatory agents, vaccines and generic pharmaceuticals. American Home Products Corporation is one of the world's largest research-based pharmaceutical and health care products companies, and is a leading developer, manufacturer and marketer of prescription drugs and over-the-counter medications.

The aforementioned draft guidance provides procedures that sponsors can use to submit promotional materials to the Agency for products that are approved under the accelerated approval regulations [21 CFR 314.550 and 601.45]. The draft procedures provide reasonable direction in this regard. However, we believe that fast track products are not necessarily subject to all provisions of accelerated approval regulations. Section 506(b)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) states:

> "Approval of a fast track product under this subsection **may** (emphasis added) be subject to the requirements-...that the sponsor submit copies of all promotional materials related to the fast track product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials."

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The use of the verb "may" in this subsection leaves an option for the requirement for preapproval promotional materials of fast track products, as opposed to the use of a stronger verb such as "shall," which is used in other subsections of section 506 to clearly denote a requirement.[1] Many fast track products undergo a full development program, with meaningful clinical endpoints that are not surrogate markers for the respective disease. Further study of the product to verify and describe clinical benefit is not needed. This is a situation analogous to product approval under "usual" circumstances, in which a requirement for routine pre-approval of promotional materials is not deemed necessary by the Agency. Accordingly, we propose that the draft guidance note the following as footnote 2, to properly reflect language in section 506(b) of the Act:

> "Sponsors whose drug or biological product is in a fast track program that is eligible for approval under section 506(b) of the Federal Food, Drug and Cosmetic Act may also be subject to 314.50 and 601.45 and can use these procedures."

In addition, there are other categories of products that can be approved under rapid conditions but not necessarily under the accelerated approval regulations, namely, products designated for priority review, and products developed under the auspices of Subpart E regulations [21 CFR 312.80-88].[2] Again, many of these products undergo a full development program, with meaningful clinical endpoints that are not surrogate markers for the respective disease. Further study of the product to verify and describe clinical benefit is not needed, ablating the need for routine pre-approval of promotional materials. We propose that the guidance explicitly state that it is not applicable to products designated for priority review, or products developed under the auspices of Subpart E regulations, unless they are specifically approved under accelerated approval regulations. Footnote 2 of the guidance may be an appropriate place to mention this.

Wyeth-Ayerst Laboratories appreciates the opportunity to comment on the draft guidance, "Accelerated Approval Products- Submission of Promotional Materials." We look forward to the issuance of this guidance in final form.

Sincerely,

WYETH-AYERST LABORATORIES

Diane Mitrione

Diane Mitrione
Senior Director
U.S. Regulatory Affairs

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[1] See, for example, section 506(a)(3), "...within 60 calendar days....the Secretary shall determine whether the drug....meets the criteria described...".

[2] Drugs intended to treat life-threatening and severely-debilitating illnesses.

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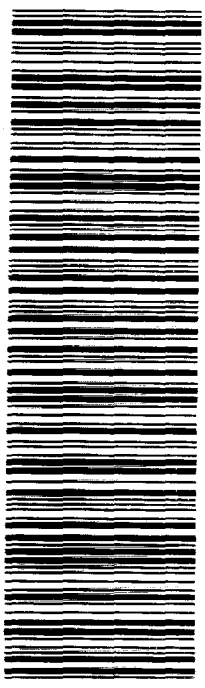

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